IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

IN RE NORPLANT CONTRACEPTIVE PRODUCTS LIABILITY LITIGATION	:	**MDL DOCKET NO. 1038** **ALL CASES**

No. 2

MEMORANDUM IN SUPPORT OF
MOTION FOR PARTIAL SUMMARY JUDGMENT
RE ADEQUACY OF THE NORPLANT LABELING

INTRODUCTION

At the heart of each of the plaintiffs' claims in this multi-district litigation is the allegation that Wyeth failed adequately to warn of a variety of side effects allegedly associated with use of the Norplant contraceptive. These failure-to-warn claims are flawed, however, for the prevailing rule is that when "a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law." *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied).

The MDL plaintiffs collectively complain of more than 950 differently described side effects.[1] But as the last four years of litigation have demonstrated, and as the Plaintiffs' Steering Committee advised the Court in 1996, the overwhelming majority of cases concern no more than a dozen side effects.[2] This motion for partial summary judgment addresses those side

---

1 Attached at Tab 35 is a listing of the side effects about which plaintiffs complain, drawn verbatim from their verified interrogatory answers.

2 At a conference in chambers, the co-chairman of the Plaintiffs' Steering Committee explained:

> So, instead of the fifty that we laid out in our complaint, we now see that by their own studies, there were only a dozen core complaints . . . .

effects plus a handful more – specifically, the 26 conditions listed as Adverse Reactions in the physician labeling (the "core" complaints) – because the Norplant warning information expressly advised healthcare providers about these conditions.[3] Particularly telling, the only obstetrician/gynecologist designated as an expert ***by plaintiffs*** has testified that the Norplant warnings address these side effects clearly and fairly and that the warnings "satisf[y] the requirements of the law."[4] Because it is indisputable that the warnings specifically include the conditions complained of, the warnings provided to physicians are adequate as a matter of law.

THE UNDISPUTED EVIDENCE

Packaged with every set of Norplant capsules is a copy of the Prescribing Information, commonly referred to as the "physician labeling." Affidavit of Margaret E. Weber, M.D., ¶ 5, Tab 32. Although Wyeth revised the physician labeling from time to time after FDA

> * * *
> We are going to resolve over ninety percent of these cases by a trial that determines their failure to warn adequately about nine symptoms, nine adverse reactions.

May 14, 1996 Informal Conference, at 21, 23, Tab 56. In the three Texas state court cases to proceed to trial, each of which involved counsel from the Plaintiffs' Steering Committee, the claims were narrowed in just this way.

3 The 26 conditions are: bleeding irregularities (specifically: many bleedings days or prolonged bleeding, spotting, amenorrhea, irregular onsets of bleeding, frequent bleeding onsets, scanty bleeding), infection at implant site, pain or itching at implant site, removal difficulties, headaches, nervousness, nausea, dizziness, adnexal enlargement, dermatitis, acne, change in appetite, mastalgia, weight gain, hair loss and hair growth, breast discharge, cervicitis, musculoskeletal pain, abdominal discomfort, leukorrhea, and vaginitis. Although the physician labeling discusses an even longer list of potential complications, this motion concerns only those complications specifically labeled as "Adverse Reactions." For analytical convenience, the many other complained-about side effects are addressed in *Motion No. 3: Motion For Partial Summary Judgment Re Conditions For Which There Is No Evidence of Causation*, filed herewith.

4 *See* p. 9, *infra*.

approval in 1990, certain warnings remained unchanged from the beginning. Thus, the fact is that the prescribing physician for *every* plaintiff received the following warning information:

ADVERSE REACTIONS

THE FOLLOWING ADVERSE REACTIONS HAVE BEEN ASSOCIATED WITH THE NORPLANT SYSTEM DURING THE FIRST YEAR OF USE. THEY INCLUDE:

MANY BLEEDING DAYS OR PROLONGED BLEEDING	27.6%
SPOTTING	17.1%
AMENORRHEA	9.4%
IRREGULAR (ONSETS OF) BLEEDING	7.6%
FREQUENT BLEEDING ONSETS	7.0%
SCANTY BLEEDING	5.2%
PAIN OR ITCHING NEAR IMPLANT SITE (USUALLY TRANSIENT)	3.7%
INFECTION AT IMPLANT SITE	0.7%
REMOVAL DIFFICULTIES AFFECTING SUBJECTS (BASED ON 849 REMOVALS)	6.2%

CONTROLLED CLINICAL STUDIES SUGGEST THAT THE FOLLOWING ADVERSE REACTIONS OCCURRING DURING THE FIRST YEAR ARE PROBABLY ASSOCIATED WITH NORPLANT SYSTEM USE:

HEADACHE
NERVOUSNESS
NAUSEA
DIZZINESS
ADNEXAL ENLARGEMENT
DERMATITIS
ACNE
CHANGE OF APPETITE
MASTALGIA
WEIGHT GAIN
HIRSUTISM, HYPERTRICHOSIS, AND SCALP-HAIR LOSS

IN ADDITION, THE FOLLOWING ADVERSE REACTIONS HAVE BEEN REPORTED WITH A FREQUENCY OF 5% OR GREATER DURING THE FIRST YEAR AND POSSIBLY MAY BE RELATED TO NORPLANT SYSTEM USE:

BREAST DISCHARGE
CERVICITIS
MUSCULOSKELETAL PAIN
ABDOMINAL DISCOMFORT
LEUKORRHEA
VAGINITIS

See the complete physician labeling at Tab 36.[5]

Dr. Anthony Lucci, plaintiffs' designated ob/gyn expert (indeed, the only ob/gyn expert named by plaintiffs in any Norplant case, federal or state), testified to the adequacy of the warnings in the first Norplant trial. About irregular menstrual bleeding, for example, Dr. Lucci acknowledged:

> Q. . . . Are the doctors informed that, "The following adverse reactions have been associated with the Norplant system during the first year of use. They include many bleeding days or prolonged bleeding," and so forth and they give you there irregular onset of bleeding? Do you see that, sir?
>
> A. Yes, I see it.
>
> Q. And do you think that is a fair warning given to the doctor?
>
> A. Well, it's a listed warning. It's fair.
>
> Q. Is it clear?
>
> A. ***It's clear.***

Trial Transcript at 156, *Alonzo v. Wyeth-Ayerst Laboratories Division of American Home Products Corporation*, Cause No. C-1679-95-F (Tex. 332d Jud. Dist. Hidalgo County), Tab 58.[6]

Dr. Lucci testified to the same effect regarding other claimed side effects:

---

[5] Also packaged with every set of Norplant capsules is a copy of the patient labeling, which Wyeth provides to physicians to assist them in counseling their patients. Weber Aff., ¶ 5, Tab 32, Tab 37. In addition to the physician and patient labeling, Wyeth made available to every physician who prescribed Norplant the Counseling Manual, *see* Tab 38, which also describes the "core" complaints as potential side effects. Weber Aff., ¶ 6, Tab 32.

[6] All references hereafter to the "Transcript" are to the trial transcript in *Alonzo v. Wyeth-Ayerst Laboratories Division of American Home Products Corporation.* One member of the Plaintiffs' Steering Committee (the Ness, Motley law firm) represented one of the five trial plaintiffs in *Alonzo* and, along with other plaintiffs' counsel in that case, jointly designated Dr. Lucci as an expert.

Q. . . . [D]o you agree, sir, that the doctors are told . . . that the warnings - that the patients are very well - the warnings - that they can suffer from prolonged episodes of bleeding? That's what it says, right?

A. Yeah, they said prolonged episodes of bleeding.

Q. Is that a fair warning to the doctor?

A. ***Yes***.

Q. All right. Is that a clear warning to the doctor?

A. ***Yes***.

* * *

Q. Let's go to the next one under nervousness and anxiety, Exhibit 1-E. Can you tell me whether or not the patient was given the warning that perhaps they would suffer from nervousness.

A. Yes.

Q. Is it a clear warning?

A. ***Yes***.

Q. Is it a fair warning received by the patient?

A. ***Yes***.

Q. The doctor, the next one, Exhibit 3-1 under prescription information, was the doctor given clear, concise and fair warnings?

A. ***Yes***.

* * *

Q. Headache. The next one is headaches. Patient labeling. . . . What listed warning is provided by the company to the – to you which you, in turn, give to the patient?

A. "Sudden severe headaches or vomiting, dizziness, or fainting, disturbances in vision or speech, weakness, or numbness in an arm or leg indicating a possible stroke."

Q. Is that a fair warning?

A. ***Yes***.

Q. Is it a clear warning?

A. ***Yes***.

* * *

Q. And Exhibit 1-E talks about, "In clinical studies women using the Norplant system have complained about the following conditions which are possibly related to the Norplant system." What's the very first one there for the patient?

A. Headaches.

Q. Is it a fair warning?

A. ***Yes***.

Q. Is it a clear warning?

A. ***Yes***.

* * *

Q. This is the prescription for the doctor. So, has – Doctor, are you complaining that you were not told by Wyeth-Ayerst that headaches could be an adverse reaction? Are you complaining about that to this jury?

A. No, I'm not. It is a listed – it's a listed warning.

Id. at 142-44, 159-60, 168 (emphasis added). In like fashion, Dr. Lucci admitted that Wyeth provided clear warnings to physicians as to hair growth and loss, *id.* at 141-42, and weight gain or loss, *id.* at 179.

When he testified as plaintiff's expert in the most recent Norplant trial on April 20, 1999, Dr. Lucci was, if anything, even more comprehensive in his approval of the Norplant warnings:

Q. When you were asked by Mr. Burns not ten minutes ago whether or not this warning provides fair and adequate information regarding the risks of insertion and removal of Norplant, you answered yes, isn't that so?

A. Yes.

Q. On the whole, looking at [it] in its totality, this warning does exactly that, doesn't it?

A. It lists – yes, it lists them all.

THE COURT: It lists what?

THE WITNESS: ***It lists all of the warnings. They are all listed there.***

THE COURT: What warnings?

THE WITNESS: ***The warnings about the side effects.***

Q. On the whole the package insert does its job adequately, doesn't it, sir?

* * *

A. ***Yes, insofar as satisfying the requirements of the law, all of the adverse effects are listed in the package insert. It does satisfy that requirement, yes.***

Trial Transcript at 796-97, *Ramirez v. Wyeth Laboratories, Inc.*, No. 94-132182 (Supreme Court of N.Y., County of N.Y.) (emphasis added), Tab 59.

ARGUMENT

I. THE CONTROLLING LAW: A WARNING THAT EXPRESSLY INCLUDES THE COMPLAINED-OF SIDE EFFECTS IS ADEQUATE AS A MATTER OF LAW.

Virtually every one of the more than 30,000 MDL plaintiffs complains that she suffered irregular bleeding of one kind or another. Most of the plaintiffs also complain of one or more of the other "core" complaints. All of these complained-about conditions, however, are identified in the "Adverse Reactions" section of the physician labeling. Regarding these prominently warned-about conditions, summary judgment is appropriate, for when "a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law." *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied).

In *Rolen*, the plaintiff developed Stevens-Johnson syndrome after using the prescription drug Allopurinol. *Id.* at 608. Rolen sued, claiming that Burroughs Wellcome's warnings were deficient because they "failed to adequately or properly warn" about the "dangerous propensities of allopurinol." *Id.* The prescribing information for Allopurinol specifically informed physicians, however, that "[i]n some instances a skin rash may be followed by more severe hypersensitivity reaction such as exfoliative urticarial and purpuric lesions as well as Stevens-Johnson syndrome." *Id.* at 609 n.2. The Court of Appeals affirmed the trial court's grant of summary judgment for Burroughs Wellcome, holding that plaintiff's claim failed as a matter of law because "the warning clearly included the reaction suffered by *Rolen*." *Id.* at 609.

Two cases involving contraceptives are directly on point. In *Upjohn Co. v. MacMurdo*, 562 So. 2d 680 (Fla. 1990), the plaintiff was prescribed Depo-Provera -- like Norplant, a progestin-only contraceptive, the principal difference being that the hormone is delivered by an injection every three months. Following MacMurdo's second Depo-Provera injection, she began to experience "continuous menstrual bleeding." *Id.* at 681. Not realizing that Depo-Provera was likely the cause of these menstrual irregularities, MacMurdo's physician diagnosed her as suffering from "dysfunctional bleeding" and performed a hysterectomy. *Id.* at 683. MacMurdo sued, and both she and her physician alleged that Upjohn had failed to provide adequate warnings. The Depo-Provera physician labeling provided in pertinent part:

> THE FOLLOWING ADVERSE REACTIONS HAVE BEEN OBSERVED IN WOMEN TAKING PROGESTIN INCLUDING DEPO-PROVERA:
>
> BREAKTHROUGH BLEEDING
> SPOTTING
> CHANGE IN MENSTRUAL FLOW

Id. at 682. MacMurdo maintained that this warning was deficient because it did not specifically describe the irregular bleeding as "excessive, continuous, or prolonged" in just those words. *Id.*

at 683. The Florida Supreme Court rejected this contention, finding Upjohn's warnings adequate as a matter of law because the description of menstrual irregularities in the Depo-Provera physician labeling necessarily encompassed a range of bleeding irregularities, including the type which MacMurdo experienced:

> [B]reakthrough bleeding is bleeding outside the normal menstrual period, and changes in menstrual flow refers to changes from the norm. ***The fact remains that the insert warned of the possibility of abnormal bleeding outside of the menstrual period. It would be unreasonable to hold Upjohn liable for not characterizing the bleeding as excessive, continuous, or prolonged.***

Id. (emphasis supplied). Accordingly, the court concluded that "[t]he evidence was insufficient to present a jury question on the inadequacy of the package insert to warn of the potential consequences of the use of the drug." *Id.*

Similarly, in *Eiser v. Feldman*, 507 N.Y.S.2d 386 (App. Div. 1986), the plaintiff was prescribed the oral contraceptive Ortho Novum, which, like Norplant, contains a synthetic progestin. After taking the drug, Eiser experienced nausea, dizziness, severe mood swings, and "a partial visual blockage in her right eye." *Id.* at 387. Eiser brought suit, alleging that the defendant had failed adequately to warn of the risks entailed in the use of its product. The defendant moved for summary judgment on the ground that the Ortho Novum warnings were adequate as a matter of law. The Appellate Division reversed the trial court's denial of the defendant's motion, holding that a warning that expressly includes the complained-of harm is adequate as a matter of law:

> In this case, it is clear that appellant warned plaintiff, both directly and through her physician, of the possibility of developing the very side effects of which she now complains. Visual impairment is expressly cited in the package insert and Physicians Desk Reference (PDR) entry concerning Ortho Novum as a danger associated with the drug's use.... As to plaintiff's earlier reported adverse reactions (*i.e.*, nausea, dizziness, crying and mood swings), these too are explicitly cited in the package insert and PDR.

* * *

> Although these warnings were indisputedly provided, plaintiff maintains that there is a factual question as to the adequacy that should be resolved by a jury. While the adequacy of warnings is often properly left for jury determination, there are cases, and this is one, where no triable question is raised.... ***Where, as here, express warnings have been given against the complained-of harm, bare allegations of inadequacy in those warnings are not sufficient to defeat a drug manufacturer's motion for summary judgment.***

Id. at 388 (emphasis supplied).

Rolen, MacMurdo, and *Eiser* are not at all unusual. Although courts frequently recite that the adequacy of warnings is a jury question – as it typically is – the reported cases reflect that there is no general rule precluding summary judgment in warnings cases. The fact is that plaintiffs seldom assert a failure-to-warn claim when the physician labeling expressly includes the very side effect allegedly suffered. But when they have done so, the courts have granted summary judgment. *See, e.g., Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987) (***affirming grant of summary judgment***: "We reject th[e] suggestion that a mere allegation of inadequacy in the warning of side effects on a prescription drug makes a jury issue."); *Koncz v. Burroughs Wellcome Co.*, No. 92 C 5797, 1994 WL 178320, at *4 (N.D. Ill. May 9, 1994) (***granting summary judgment***: physician labeling that "expressly indicates the potential side effects experienced by Koncz" is adequate as a matter of law); *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573, 580 (W.D. La.) (***granting summary judgment***: physician labeling that "specifically states" that the side effect plaintiff experienced "was one of the adverse reactions which had been reported" is adequate as a matter of law), *aff'd without op.*, 864 F.2d 789 (5th Cir. 1988); *Percival v. American Cyanamid Co.*, 689 F. Supp. 1060, 1063-64 (W.D. Okla. 1987) (***granting summary judgment***: "The package insert specifically warned of convulsions and encephalopathy, and warned that rarely such neurological disorders may ...

result in permanent brain damage. Young Charles Percival's injuries have been characterized by plaintiffs as 'seizure disorder,' 'infantile spasms' and 'moderate to severe retardation.' Thus the package insert warned of the very injuries suffered by Charles Percival."); *Wooten v. Johnson & Johnson Products, Inc.*, 635 F. Supp. 799, 802 (N.D. Ill. 1986) (***granting summary judgment***: physician labeling that "specifically warns of the risk of allergic (*i.e.*, anaphylactoid) reactions" adequate as a matter of law); *Goodson v. Searle Laboratories*, 471 F. Supp. 546, 548 (D. Conn. 1978) (***granting summary judgment***: "[T]his Court is compelled to find there is no issue of material fact that the defendant warned the medical profession . . . of the risk of cerebral thrombosis associated with the use of Demulen."); *Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121, 124 (W.D. Tenn. 1977) (***granting summary judgment***: "With regard to the adequacy of the warnings given, it is difficult to see how they could have been more precise or more accessible to the medical profession. The package insert and the Physicians Desk Reference entry warned specifically of the possibility of the adverse side effect which [plaintiff] allegedly suffered.").

Indeed, the courts in 38 jurisdictions have granted summary judgment or directed verdicts on the ground that warnings on their face were adequate as a matter of law.[7] *See* the state-by-state listing of cases attached at Tab 42.[8] The law of these 38 jurisdictions governs the claims of approximately 25,590 of the MDL plaintiffs.

Regarding the "core" complaints, application of the foregoing authority precludes each of the plaintiffs from maintaining her claims with regard to any of these side effects.

---

7 The 38 jurisdictions include 36 states, Puerto Rico, and the District of Columbia.

8 In the remaining 13 states with MDL plaintiffs, there are no reported cases deciding the issue of adequacy of the warnings as a matter of law, but also no cases ruling out such a decision in an appropriate situation. Approximately 4395 plaintiffs are governed by the law of these states.

II. THE UNDISPUTED, DISPOSITIVE FACTS: THE NORPLANT WARNINGS PROVIDED TO PHYSICIANS EXPRESSLY INCLUDE THE "CORE" COMPLAINTS.

A. The Warnings Include the Possibility of Irregular Menstrual Bleeding.

The verified interrogatory answers reveal that, as was true of the five bellwether plaintiffs, virtually every plaintiff complains that Norplant caused her to experience menstrual bleeding irregularities. The allegations of the bellwether plaintiffs are representative. Beverly McDaniel alleged that she had "changes in [her] menstrual cycle," that "some months [she] wouldn't even have a cycle," and that when she did have her period, "it was heavy." McDaniel Depo. at 172, Tab 94. Jennifer Burton claimed that her period "was different every time," that "[s]ometimes it would be twice a month," that other times "[i]t would be once a month," and that sometimes she "would miss a month." Burton Depo. at 21, Tab 93. And Kristy Youngblood claimed that after the first month, she had "spotting" or "bleeding" every day until she had Norplant removed. Youngblood Depo. at 89, Tab 95.

Menstrual bleeding irregularities, however, are a common side effect, not only of Norplant, but also of progestin-containing contraceptives such as birth control pills and Depo-Provera. The Norplant clinical trials revealed that more women discontinued use of the product due to bleeding irregularities than all other side effects combined (a statistic that Wyeth includes in the physician labeling).[9] Accordingly, the Norplant warnings place significant emphasis on this possible adverse event, providing in pertinent part:

> **ADVERSE REACTIONS**
>
> THE FOLLOWING ADVERSE REACTIONS HAVE BEEN ASSOCIATED WITH THE NORPLANT SYSTEM DURING THE FIRST YEAR OF USE. THEY INCLUDE:
>
> | | |
> |---|---|
> | MANY BLEEDING DAYS OR PROLONGED BLEEDING | 27.6% |
> | SPOTTING | 17.1% |

[9] Tab 36 (Table 3: Annual and Five-Year Cumulative Rates per 100 Users).

AMENORRHEA	9.4%
IRREGULAR (ONSETS OF) BLEEDING	7.6%
FREQUENT BLEEDING ONSETS	7.0%
SCANTY BLEEDING	5.2%

Tab 36. The physician labeling further highlights this potential side effect by including an additional discussion of bleeding irregularities in the Section labeled "Warnings":

> **WARNINGS**
>
> A. WARNINGS BASED ON EXPERIENCE WITH THE NORPLANT SYSTEM
>
> 1. BLEEDING IRREGULARITIES
>
> MOST WOMEN CAN EXPECT SOME VARIATION IN MENSTRUAL BLEEDING PATTERNS. IRREGULAR MENSTRUAL BLEEDING, INTERMENSTRUAL SPOTTING, PROLONGED EPISODES OF BLEEDING AND SPOTTING, AND AMENORRHEA OCCUR IN SOME WOMEN.

Id. In short, it is indisputable that the warning information furnished to health care providers addresses the possibility of irregular menstrual bleeding explicitly, repeatedly, and with special emphasis.

B. The Warnings Also Include the Possibility of Infection at Implant Site, Pain or Itching at Implant Site, Removal Difficulties, Headaches, Nervousness, Nausea, Dizziness, Adnexal Enlargement, Dermatitis, Acne, Change in Appetite, Mastalgia, Weight Gain, Hair Loss and Hair Growth, Breast Discharge, Cervicitis, Musculoskeletal Pain, Abdominal Discomfort, Leukorrhea, and Vaginitis.

Plaintiffs allege that they also experienced a variety of side effects apart from menstrual irregularities. Although no two plaintiffs allege precisely the same combination of side effects, collectively they allege in large numbers that they suffered infection at the implant site, pain or itching at implant site, removal difficulties, headaches, nervousness, nausea, dizziness, adnexal enlargement, dermatitis, acne, change in appetite, mastalgia, weight gain, hair loss and hair growth, breast discharge, cervicitis, musculoskeletal pain, abdominal discomfort, leukorrhea, and vaginitis. Like irregular bleeding, each of these conditions is specifically

included in the Norplant physician labeling, which lists all of these conditions as "Adverse Reactions," and in accompanying materials.[10]

Thus, where the "core" complaints are concerned, the Norplant warnings "specifically mention[] the circumstances complained of" by most of the plaintiffs. For that reason, the warnings are "adequate as a matter of law." *See* cases cited at pp. 9-13, *supra*, and at Tab 42.

C. Plaintiffs' Ob/Gyn Expert Admits the Warnings Are Adequate.

Dr. Anthony Lucci, the only ob/gyn expert ever designated as an expert by the MDL plaintiffs (or plaintiffs in any Norplant case)[11] has admitted that the Norplant physician and

---

[10] In the patient labeling provided to physicians, the conditions are listed under sections entitled "Side Effects of the Norplant System," "Warnings Signals," and/or "Risks of Using the Norplant System." Tab 37. And the Counseling Manual emphasizes the potential for these side effects, explaining that "[i]n addition to menstrual bleeding irregularities, women using the Norplant system have reported the following conditions during the first year, which may be method-related: headache, nervousness, nausea, dizziness, adnexal enlargement, dermatitis, acne, appetite change, mastalgia, weight gain, hirsutism, hypertrichosis, scalp-hair loss and hyperpigmentation at the insertion site." Tab 38, at 12. It also cautions that "[w]arning signs of possible problems" include "severe abdominal pain," "arm pain," and "episodes of migraine headache or other repeated severe headaches." *Id.* at 16.

[11] State plaintiffs designated Dr. Lucci as an expert in the *Morales* case (Hidalgo Co., Texas); *Davis* case (Jefferson Co., Texas); *Gaytan* case (Cameron Co., Texas); *Meier* case (Harris Co., Texas); *Alexander* case (Greene Co., Alabama); *Harper* case (Marion Co., Indiana); and *Ramirez* case (New York). The MDL plaintiffs also designated a family practice physician, Dr. John Haynes, as an expert. But although critical of the labeling, Dr. Haynes admitted that he is not an expert in labeling matters:

> A. ***And I don't want to criticize [Wyeth] because I'm not an expert in how to label these things, nor do I know what the law is that concerns doing that.*** All I'm saying is that I really wish that I would have been able to tell my patients that, you know . . . the numbers have showed that you'll have a tenfold increase in having some mood disorder.
>
> * * *
>
> So that's – if that's a criticism, I guess it is . . . – I mean it from the perspective of a practicing physician. ***I don't***

patient labeling lists these very side effects and, in almost every instance, he further concedes that the warnings are clear and fair. Only last month, Dr. Lucci testified:

> Q. On the whole the package insert does its job adequately, doesn't it, sir?
>
> * * *
>
> A. Yes, insofar as satisfying the requirements of the law, all of the adverse effects are listed in the package insert. It does satisfy that requirement, yes.

Trial Transcript at 796-97, *Ramirez v. Wyeth Laboratories, Inc.*, Case No. 94-132182 (Supreme Court of N.Y., County of N.Y.), Tab 59.

CONCLUSION

In their verified interrogatory answers, plaintiffs casually attribute hundreds of different maladies to Norplant. As plaintiffs' counsel acknowledge, however, at the heart of these cases are little more than a dozen side effects about which nearly every plaintiff complains. If plaintiffs cannot recover for these side effects, then, as a practical matter, plaintiffs have no case.

As to all the MDL plaintiffs, Wyeth is entitled to partial summary judgment that the Norplant warnings are adequate as a matter of law for the "core" complaints – menstrual bleeding irregularities, infection at implant site, pain or itching at implant site, removal difficulties, headaches, nervousness, nausea, dizziness, adnexal enlargement, dermatitis, acne, change in appetite, mastalgia, weight gain, hair loss and hair growth, breast discharge, cervicitis,

---

> ***know what's supposed to be on the labelings, per se, as far as legally.***

Haynes Depo. at 187, 194 (emphasis added), Tab 97. For this reason and others, *see* Memorandum in Support of Defendants' Motion to Exclude Expert Testimony, at 56-60, Dr. Haynes' expert testimony would be inadmissible under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *E.I. DuPont deNemours & Company, Inc. v. Robinson*, 923 S.W.2d 549 (Tex. 1995).

musculoskeletal pain, abdominal discomfort, leukorrhea, and vaginitis – because the Norplant warnings specifically address these very conditions.

Respectfully submitted,

GERMER & GERTZ

By: _____
Paul W. Gertz

805 Park Street
P.O. Box 3728
Beaumont, Texas 77704

WILLIAMS & CONNOLLY

John W. Vardaman
F. Lane Heard III

725 Twelfth Street, N.W.
Washington, D.C. 20005
(202) 434-5000

Attorneys for Defendants

Of Counsel:

William J. Ruane
American Home Products Corp.
Five Giralda Farms
Madison, NJ 07940-0874

Frank T. Rivas
Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101-8299

Dated: May 24, 1999

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was forwarded to all counsel of record on this 24th day of May, 1999 as follows:

Chris Parks, Esq.
Parker and Parks, L.L.P.
1 Plaza Square
Port Arthur, Texas 77642-5513

VIA HAND DELIVERY

Roger P. Brosnahan, Esq.
Brosnahan, Joseph & Suggs
Suite 500
701 Fourth Avenue South
Minneapolis, Minnesota 55415

VIA REGULAR MAIL

Turner W. Branch, Esq.
The Branch Law Firm
2025 Rio Grande Boulevard, N.W.
Albuquerque, New Mexico 87104

VIA REGULAR MAIL

Paul W. Gertz